



STATE OF WASHINGTON
DEPARTMENT OF HEALTH

March 4, 2010

Donald Black, Attorney
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1602 Fifth Avenue, #2100
Seattle, Washington 98101-1686

Dear Mr. Black:

Thank you for your Determination of Non-Reviewability (DOR) request received on February 11, 2010, related to new procedures proposed to be provided by Grays Harbor Community Hospital. Below are the facts relied upon by the Certificate of Need Program in reaching its conclusion regarding your DOR request.

FACTS

- Grays Harbor Community Hospital (GHCH) is located at 915 Anderson Road in Aberdeen, within Grays Harbor County and holds a license for 140 acute care beds.
- Services currently provided at GHCH include general inpatient medical/surgical, diagnostic/therapeutic services, critical care, chemical dependency, emergent, pediatric level one, and rehabilitation services. The hospital also provides a variety of outpatient services including chemical dependency and surgical.
- This DOR proposes that GHCH would establish a new interventional vascular laboratory within space at the hospital.
- GHCH and physician investors who are members of GHCH's active medical staff have created a new limited liability corporation known as Interventional Lab Services, LLC.
- The new lab would be equipped under contract with Interventional Lab Services, LLC, which includes purchase or lease of equipment.
- Interventional Lab Services, LLC would be solely responsible for providing all necessary medical equipment, supplies, staff, and other inputs necessary for the provision of services in the new lab.
- GHCH would be responsible for conducting ongoing quality assurance and utilization review procedures; payment of all expenses incurred with the performance of interventional vascular services that are not the responsibility of the new company, providing appropriate and suitable space for the services, providing all necessary patient information systems, and billing/collecting for all services provided in the new lab.
- Services to be provided in the new laboratory include PICC line placement, uterine fibroid embolization, peripheral vascular studies, aortogram/angiogram, and ultrasound-guided access.



CONCLUSION

Based on the above factual information provided by you, the Certificate of Need Program concludes that the establishment of a new interventional vascular laboratory at GHCH is not subject to Certificate of Need review.

Please note: This determination is not transferable and is based on the facts submitted in your request. Prior Certificate of Need review and approval may be required under the provisions of WAC 246-310-020 if changes occur in the facts as presented. Prior Certificate of Need review and approval may be required under the provisions of WAC 246-310-020 if any of the following changes occur:

- 1) should you later decide to expand services to include services outlined in WAC 246-310-705(4). Specifically, percutaneous coronary interventions (PCI), which is invasive but nonsurgical mechanical procedures and devices that are used by cardiologists for the revascularization of obstructed coronary arteries. These interventions include, but are not limited to:
 - (a) Bare and drug-eluting stent implantation;
 - (b) Percutaneous transluminal coronary angioplasty (PTCA);
 - (c) Cutting balloon atherectomy;
 - (d) Rotational atherectomy;
 - (e) Directional atherectomy;
 - (f) Excimer laser angioplasty;
 - (g) Extractional thrombectomy.
- 2) should you decide to expand the scope of services to include services subject to Certificate of Need review under the provisions of WAC 246-310-020.
- 3) should GHCH or the laboratory be purchased or leased.

This determination of non-reviewability does not constitute approval under any other local, federal, or state statute, or implementing rules and regulations. Examples where additional approval may be necessary include, but are not limited to, construction plan approval through the Construction Review Section of the Department of Health, facility licensing/certification through the Department of Health, and other federal or local jurisdiction permits.

Please call me at (360) 236-2957 if you have any further questions as you proceed with this project and establishment of the new lab.

Sincerely,



Karen Nidermayer, Analyst
Certificate of Need Program
Office of Certification and Technical Support

cc: Linda Foss, DOH, Investigations and Inspections Office